

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

**THIS PAGE BLANK (USPTO)**



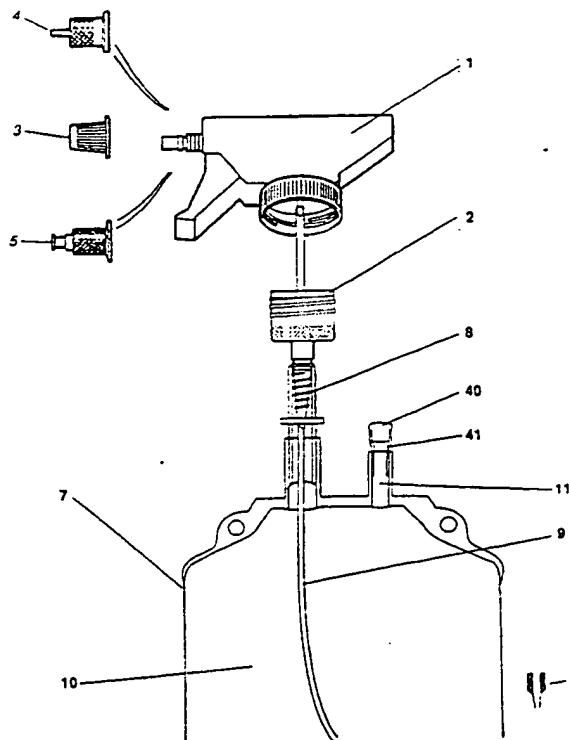
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : A61M 3/02, 11/00, 39/10		A2	(11) International Publication Number: WO 95/13105
			(43) International Publication Date: 18 May 1995 (18.05.95)
(21) International Application Number: PCT/GB94/02436		(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LT, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ).	
(22) International Filing Date: 7 November 1994 (07.11.94)			
(30) Priority Data:			
9323080.3	9 November 1993 (09.11.93)	GB	
9412814.7	25 June 1994 (25.06.94)	GB	
9414917.6	25 July 1994 (25.07.94)	GB	
9417896.9	6 September 1994 (06.09.94)	GB	
(71)(72) Applicant and Inventor: MILLS, Nicholas, John [GB/GB]; Kingsbank Farmhouse, Kingsbank Lane, Beck- ley, Nr. Rye, East Sussex TN31 6RU (GB).		Published Without international search report and to be republished upon receipt of that report.	

(54) Title: SECURE ADAPTOR FOR STERILE FLUID PACKS WHICH ALLOWS THEIR USE IN WOUND AND MEDICAL LAVAGE

## (57) Abstract

This invention relates to a secure adaptor for sterile fluid packs to allow a variety of uses in the field of wound and medical lavage. A tight and secure fit is made possible by a coarse thread that is screwed in and grips the inside wall of the giving set port. Further design features prevent leakage of the sterile fluids. A trigger sprayer can be joined to the secure adaptor. Conveniently the joining screw thread can also fit the screw thread tops of free standing plastic bottles containing sterile saline. A sterile surgical spray unit is thus produced. A sterility security device can be incorporated into the design of the spray unit and secure adaptor which enables them to be "screwed in" but not easily removed from the plastic bottles or fluid bags. The secure adaptor can be joined to a variety of medical catheters. A wound lavage teaching aid has been designed to demonstrate the use of this sterile surgical spray unit.



**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

SECURE ADAPTOR FOR STERILE FLUID PACKS WHICH ALLOWS THEIR  
USE IN WOUND AND MEDICAL LAVAGE

This invention relates to a secure adaptor for intravenous fluid packs and pour bottles containing sterile fluids which can extend the use of such fluids for a variety of uses in the field of wound and medical lavage.

The features and advantages of this invention will become apparent from the following detailed description with reference to the accompanying drawings in which;

Fig 1 shows the secure adaptor 2 attached to the inside wall of the giving set port of a typical sterile fluid pack. It shows attachment of the secure adaptor to a trigger sprayer and the special adaptors 4,5 and 6 which enable the device to be connected to sterile needles and catheters.

Fig 2 illustrates the secure adaptor which incorporates a tapered end 11, for ease of introduction into the giving set port, a coarse screw thread 12, which strongly secures the adaptor to the inside of the giving set port of a typical sterile fluid pack. The secure adaptor incorporates several design features which prevent the leakage of fluid.

Fig 3 shows the secure adaptor attached to a stepped end 16, which enables attachment to a variety of catheters.

Fig 4 illustrates how the secure adaptor can be joined to

a shaped device 46, for insertion into the rectum.

Fig 5 illustrates how a sterility security device can be fitted to the connecting screw thread 17, of the trigger sprayer to enable the trigger sprayer 1, to be screwed on to but not screwed off the secure adaptor.

Fig 6 shows how the sterility security device can be incorporated into the secure adaptor for attachment to a variety of catheters.

Fig 7 illustrates a variation of the secure adaptor for introduction into the giving set port of sterile irrigation packs.

Fig 8 shows a further variation of the design of the secure adaptor for the introduction into sterile irrigation packs.

Fig 9 shows how an eyebath can be attached directly onto the screw thread at the top of a sterile pour bottle. An alternative design incorporates a dip tubing which extends from an eyebath into the fluid contained in the pour bottle. This device can incorporate the sterility security device which would enable it to be screwed on but not screwed off the pour bottle.

Fig 10 illustrates how an eyebath can be attached to a sterile trigger sprayer for lavage of the eye.

Fig 11 illustrates the eye bath sprayer in use.

Fig 12 shows how the sterile trigger sprayer can be attached to a hand-held brush and the sterile fluids allowed through the brushes bristles.

Fig 13 shows how the sterile spray unit can be attached to

a porous comb.

Fig 14 illustrates a teaching aid for the teaching of wound lavage.

Fig 15 shows an on-off tap incorporated into the secure adaptor.

Fig 16 shows an on-off tap incorporated into a secure adaptor for joining to a variety of catheters.

Fig 17 shows the design of sterile packaging for the sterile spray unit which incorporates a curved edge 50, for close contact with body parts for used irrigation fluid to drain into.

Fig 18 shows a concentric ring design, 51, which can be incorporated into a design on the outside of the packaging tray to enable calibration of pressures of the sterile spray unit.

Fig 19 shows how the dip tubing 9 passes through the special adaptor into the sterile fluid and is joined to the pump mechanism of the trigger sprayer.

Fig 20 illustrates how the standard plastic top of an irrigating pour bottle can be adapted to form an eye bath either by covering the existing top with a secure soft rubber sleeve or plastic sleeve 48, which fits over the plastic top or by redesigning the existing plastic top 46, in order for it to become a suitable water-tight eyebath 47 but still retain the tops features of flexible lugs 49.

Sterile isotonic saline solutions and other solutions eg: glucose saline and Hartman's solution are already

available to Doctors and Veterinary Surgeons in the form of sterile intravenous fluid packs, 7, shown in Fig 1.

These fluids are sterile and are packed in flexible plastic containers. Such containers are often made of polythene or pvc, 7.

These intravenous fluid packs have a standard "port", 8, which is designed to accept the plastic end of a standard "giving set" from where the fluids can be given via an intravenous fluid line to the patient.

According to the present invention an adaptor, 2, has been designed which enables the dip tubing, 9, of a commercially available trigger sprayer, 1, to enter the sterile solutions, 10, in the intravenous fluid packs and pump the sterile solutions at suitable pressures for wound lavage or at a gentler pressure for maintaining tissue hydration during surgery. This lavage system can be operated in an entirely sterile way and the complete unit can be lifted, directed and operated by using just one hand.

The invention also enables the attachment of the trigger sprayer to a wide variety of readily available commercial catheters to enable sterile fluid irrigation for a wide variety of medical and surgical conditions. Such adaptors, 4 and 5, can be of luer or record design and are designed to fit the male or female connections for the wide variety



of commercially available catheters.

The adaptor, 2, described in the present invention uses the inside wall of the "giving set port" to provide a secure anchorage for the adaptor. The adaptor is designed to fit tightly inside this "giving set" port, 8.

The intravenous fluid packs also normally incorporate an additive port, 40, which has a rubber seal, 41.

In the current adaptor design this tight and secure fit is made possible by the coarse thread that is screwed in and grips the inside wall of the giving set port.

Other adaptor designs would be possible including a gently tapering design which would provide a "push fit" or alternatively the surface of the adaptor could have backwards pointing barbs which would contact the inside wall of the giving set.

The adaptor could have a series of concentric rings which would contact against the inside wall of the giving set port.

The design could be a combination of several of these features.

The current adaptor has a shoulder which pushes against the top of the giving set port to ensure a good seal and to

reduce the chances of any fluids leaking from the giving set port.

The adaptor can also be securely fitted into the additive port. In this case the top of the additive port has to be cut using sterile scissors before the secure adaptor is screwed into place.

A flexible plastic "dip tube" 9, passes through the centre of the adaptor. The length of this dip tubing can be altered depending on the size of the intravenous fluid pack being used. Common sizes for these intravenous giving packs of fluids are 250mls, 500 mls and 1000 mls (half litre and one litre). The top of the adaptor consists of a coarse screw thread which is designed to fit the screw thread of the commercially available trigger spray assembly, 1.

The technical specifications of a typical commercially available trigger spray unit, 1, are as follows:

The trigger sprayer should be made mainly of copolymer polypropylene which has good physical properties and is adaptable to temperature changes. Any springs and balls in the design should be of stainless steel and if necessary the pumping element and seals should be made of NBR rubber. Trigger sprayers are readily commercially available. Suitable examples of commercially available trigger

sprayers for use with this sterile spray unit are the Bepak Trigger Spray 0176 produced by Bepak plc Kings Lynn Norfolk or the Alta 33 Trigger Sprayer sold by Englass Ltd, Scudamore Road, Leicester, England.

The trigger sprayer should be easy to handle and pump and should incorporate designs which mean that no leakage occurs even when the bottle/intravenous fluid bag is upside-down and the lever depressed.

The closure is mechanical, by screwing-on of the nozzle ring and by regulating the same, a fine mist to a powerful jet is possible.

The nozzle of the commercially available trigger sprayer, 3, can be adjusted to produce a fine spray which would be suitable for keeping tissues moist during surgery, eg: during abdominal surgery where the intestines and some of the internal organs are prone to dehydration.

The trigger sprayer can be designed to be made entirely of copolymer polypropylene which enables it to be more readily "re-cycled".

The nozzle of the commercially available trigger sprayer, 3, can also be adjusted to produce a concentrated stream of fluid between 1 and 25 p.s.i. pressure, depending on the adjustment. Such a stream of sterile fluid would be very suitable for wound lavage of a contaminated wound.

The calibration of the various pressures that can be achieved by the variable nozzle of the trigger sprayer can be shown simply in the field by a sample "target" looking rather like an archery target and working on the basis that the most powerful, highest p.s.i. stream is concentrated and if the sterile-spray unit is held at a fixed distance from such an archery target then the highest p.s.i. spray would not spread further than the "bullseye", whereas lower p.s.i. pressures would spread more widely across the width of the archery target thus providing a rough but useful guide to the pressures of the trigger spray unit. This archery target, 51 could be incorporated into the packaging design as shown in Fig 18.

Some clinicians favour the idea of adding certain antiseptics or antibiotics to the sterile intravenous packs. Such antiseptics or antibiotics can be easily and accurately added to the lavage fluid via the additive port of the standard intravenous fluid pack.

Povidone-iodine and chlorhexidine are examples of suitable antiseptics. Research has shown that they should be used in low concentrations to avoid tissue cytotoxicity. Such antiseptics could be accurately measured and added via the "additive port" which is also found in the standard design of an intravenous fluid pack.

Antibiotics eg: soluble penicillin or gentamycin could

also be added to the intravenous fluid pack via the additive port, 11, if the clinician so wished.

The current adaptor is made of surgical grade stainless steel which is suitable for re-sterilisation by steam autoclave and re-use. It is envisaged that the adaptor could be moulded in high grade plastic to produce a unit which is disposable. Such a unit would be sterilisable by gamma irradiation or by ethylene oxide sterilisation..

If such a unit was produced in disposable form, it could be packaged in a see-through package such as the commercially available "sbw view-pack" (LMG Brothers Limited). Alternatively the packaging would be made of a moulded, rigid or semi-rigid, transparent plastic tray which could conveniently store the sterile spray unit and associated adaptors. These associated adaptors could be stored in individual compartments within the tray and the sterile seal paper could be peeled off each individual compartment so that the remaining adaptors within the tray would stay sterile. When covered with sealed paper this tray would be a suitable container for ethylene oxide sterilisation, gamma irradiation sterilisation or possibly steam sterilisation. This tray could be used for the wound lavage fluid to drain into after it has lavaged the wound. The edge of the plastic tray packaging could be formed in a curved shape, 50 so that it would closely fit any part of human or animal anatomy which would enable easier drainage

of the lavage fluid. Such a 'tray' would also be a useful receptacle for the used adaptors, cotton wool etc. used during the wound lavage process. Such a packaging tray is illustrated in Fig 17.

The packaging tray which has one or more edges shaped to conform to the patients body can be used in conjunction with any product associated with wound lavage e.g. Intrasisite Gel [Trademark Smith and Nephew], a premixed hydrojel wound dressing, can be used in conjunction with the wound lavage device described in this invention in a novel way. The Intrasisite Gel contained in the new Applipak plastic dispenser could be placed in a plastic tray as described previously in this invention and when covered with a sealed paper this tray would be suitable for sterilization.

The edge of this plastic tray packaging could be formed in a curved shape, 50 so that it would closely fit any part of the human or animal anatomy.

When treating a wound the clinician could squeeze the intrasisite gel into the wound.

The skin edges of the wound could then be clipped of hair and carefully cleaned using a suitable antiseptic.

These suitable antiseptics are very useful for cleaning skin edges and the skin around the wound but have the disadvantage of being cytotoxic to the cells within the wound. However in this case such cells are physically protected by the intrasisite gel from the cytotoxic effects of such antiseptics. Any hair or debris from the clipping of

the skin would fall onto the Intrasite Gel layer covering the wound.

The wound could then be copiously lavaged to remove the Intrasite Gel and any contained debris. The packaging tray could be used to drain the used wound lavage fluid into and the tray would also act as a useful container for the disposal of the waste.

The wound lavage device described in this invention could also be used at Intrasite Dressing changes where the pressure variations encompassed within the design of this device would allow very gentle wound lavage which would leave the delicate epithelial cells, encouraged by the moist wound dressing regime, to remain relatively undisturbed.

The nozzle of the commercially available trigger sprayer is attached to the sprayer using a screw thread.

The invention also comprises two nozzle adaptor units, 4 and 5. These screw onto the screw thread of the trigger sprayer.

One of these screw-on nozzle adaptors is suitable for direct connection to hypodermic needles and the other is designed to accept either luer or record connections. Such a connection could be used to join the now adapted trigger sprayer to an extension giving set such as the Aquapharm Avon tubing extension set.

The adapted trigger sprayer with the two nozzle attachments could be used to flush tendon sheaths and joints.

These nozzle attachments, 4 and 5, would enable the adapted trigger sprayer unit to be connected to the whole range of commercially available catheters and irrigation attachments which would enable sterile fluids from commercially available intravenous fluid packs to be used for the irrigation of other organs ranging from chronic leg ulcers, to the external auditory meatus, bladder irrigation, as a sterile enema method, to irrigate mammary glands, (this is thought to be particularly suitable for toxic mastitis in cows), as a first-aid method for cleansing the eye, for the sterile flushing of sinuses, for flushing puncture wounds, for the treatment and lavage of bite wounds, for the sterile lavage of rectal tears, for the sterile lavage of open fractures.

It is envisaged that the unit would have a very wide variety of medical, veterinary and dentistry functions.

In this description these nozzle adaptors 4 and 5, use the screw-thread to attach to the trigger sprayer, 1, however it is envisaged that "push on" or "clip on" attachments could also be used.

The unit can be sterilised by ethylene oxide sterilisation, gamma irradiation or possibly by steam sterilisation.



The ethylene oxide sterilisation can be done commercially by companies such as Griffiths Microscience, Cotes Park, Somercotes, Derbyshire DE55 4NJ, who use a very carefully controlled process to ensure biological sterility.

A further use for this wound and medical lavage system would be by using an adaptor, 6, into which the dip tubing, 9, is securely pushed. The other end of the adaptor, 6, would be formed to accept either record or luer fitting hypodermic needles or commercially available catheters. The unit could thus be used to 'drain' fluid, eg: haematomas or seromas or to actively drain during eg: tendon sheath lavage. Such a system could be used synchronously with a similar system in 'lavage' mode to provide a simultaneous active "lavage" and "draining" system.

A further design of the current adaptor is illustrated in Fig 2 in which the tight and secure fit is made possible by the coarse thread that is screwed in and grips the inside wall of the giving set port. The thread is tapered with a plain tapered start to the thread, 11, which enables easy introduction of the adaptor into the giving set port. Conveniently, the plain tapered start to the thread 11, ends at a suitable distance so that the thread starts to contact the inside of the giving-set port when the end of the secure adaptor touches the seal. The screw action then readily breaks the seal.

The coarse screw thread which is screwed in and grips the inside wall of the giving set port is designed to be cut into the adaptor, 12, to be a design feature to prevent leakage of the intravenous fluids from the intravenous fluid pack around the screw threads.. The adaptor also incorporates a concentric ring or 'stop' which acts as a further design feature to prevent leakage of the intravenous fluids from the intravenous fluid pack. When the adaptor is screwed into the giving set the polythene expands over this concentric ring or stop, 13, to provide a very tight fit. Further concentric rings can be added to the design if required. The design also incorporates a 'shoulder', 14 which acts as a further design feature to prevent leakage of the intravenous fluid from the intravenous fluid pack.

The top of this adaptor consists of a coarse screw thread which is designed to fit the screw thread of the commercially available trigger spray assembly, 1.

As mentioned previously, in this invention, this secure adaptor can be used to join the intravenous fluid pack to a variety of catheters for medical and veterinary use.

Fig 3 shows such an adaptor that is designed to fit into a variety of catheters via a stepped ring termination, 16.

A veterinary use for such an adaptor is to join it to a

foley catheter. This combination can be used to "wash-out" mares during obstetrical procedures. The adaptor described in this invention can be used to join a 1 litre, 2 litre or other conveniently sized intravenous fluid bag to such a foley catheter which can be securely anchored to the inside of the cervix by the expandable balloon. This balloon can be expanded by water to hold it accurately inside the mares cervix.

The intravenous fluid pack can be warmed to body temperature by immersing the unopened intravenous fluid pack in water at the required temperature. The outer pack can then be opened and the inner sterile, warmed pack can have the giving set port opened to allow the adaptor to be securely attached to the inside of the giving set port.

The sterile intravenous fluid, eg: isotonic saline, can then be infused into the mares uterus and then siphoned back into the empty intravenous pack. This device can incorporate an on/off tap so that it can be screwed into the giving-set ports without spillage as illustrated in Fig 16.

The intravenous pack is normally made in clear plastic and so the siphoned out fluid can be carefully examined, if necessary under magnification to provide a usefully clinical aid for this type of lavage.

Because this type of lavage system is performed under sterile conditions the siphoned out fluid can be taken for bacteriological examination.

This type of lavage can be for human urology.

The secure adaptor described in this invention can also be joined to the "sterile water for irrigation" packs as produced by Baxter Healthcare. The "sterile water for irrigation packs" and "intravenous fluid packs" are normally packed in a transparent plastic bag. This outer bag can be opened in a sterile way so that the nurse or surgeon can use the sterile surgical spray unit or adaptors in a totally sterile manner. See Fig 7 and Fig 8.

As mentioned previously the secure adaptor can be joined to any medical catheter or device.

One such device is to join the adaptor to a suitable enema catheter, as shown in Fig 4, which would enable the adaptor to be used for such uses as colonic lavage, for the treatment of constipation and for the introduction of radiographic markers. For these uses some of the intravenous fluid can be drawn off and specialist drugs or fluids introduced if necessary via the additive port of the intravenous fluid bag. This enema catheter could incorporate an "on/off" tap as shown in Fig 15 so that it could be screwed into the giving-set port without spillage.

The "on/off" tap could itself incorporate a "sterility security device" in the form of a "one-way ratchet" and a stop. This would ensure that the "on/off" tap could only be turned in one direction for less than 360 degrees. Such a design would ensure single use only.

Sterile water and saline are also commonly produced in screw-topped, free-standing plastic bottles by eg: Baxter Healthcare. Such plastic bottles have a screw top. The trigger sprayer described in this invention can be sterilised, stored in a sterile pack and screwed into such a free-standing plastic container to form a sterile surgical spray unit.

The screw thread of the trigger sprayer, 21, can conveniently be the same internal diameter and screw type to fit the screw thread of such a free standing plastic container as well as the screw thread of the secure adaptor, 15, as shown in Fig 2.

The screw thread of the trigger sprayer can also have an adaptation as shown in Fig 5 in which a sterility security device is incorporated which allows the trigger sprayer to be screwed onto the screw top of the plastic bottle containing the sterile water, saline or other suitable fluid but not be readily screwed off.

Such a sterility device consists of two parts, an internal

part, 24, which consists of an internal screw thread, 23, which is designed to securely fit the external diameter screw thread of the plastic bottle or the secure adaptor, 15, and external circular part which has raised radiused cogs, 19, around the external circumference. Each of these cogs has a flat back section, 20. Such a device interconnects with the second part, 25, to form a one-way ratchet.

In this second part of the device the internal diameter has flexible flanges, 22, which interconnect with the flat surfaces, 20. This means that such a trigger sprayer can be screwed onto the secure adaptor, 15, and also the plastic bottle containing suitable sterile solutions but not easily screwed off. This system has the advantage that the inadvertent re-use of non sterile spray units is more difficult with resultant benefits in patient protection. The system therefore acts as a sterility security device.

The secure adaptor mentioned in this invention which in one form screws into the giving set port of the intravenous fluid pack can also incorporate this sterility security device. This means that the secure adaptor can be easily screwed into the giving set port of an intravenous fluid pack but the sterile security device prevents the screw thread from undoing as the ratchet arrangement described and shown in Fig 5 does not engage when turned in an anti-clockwise (unscrewing) direction.

Fig 6 shows a further design for the secure adaptor in which the tapered end, 26, is bevelled to allow the seal inside the giving set port to be readily broken. The distance between this bevelled end, 26, and the start of the screw thread, 27, can be designed to facilitate the breaking of this seal by means of the thread engaging the inside of the polythene giving set port at the correct distance for the easy breaking of this seal.

The sterility security device can be incorporated into the design of the secure adaptor as shown in Fig 6.

The sterility security device could be further strengthened if the end of the standard giving set port had an external screw thread which joined with a further screw thread on the secure adaptor. As the giving set port would have an external thread only it would not interfere with the traditional giving set arrangement but would further strengthen the sterility security device mentioned in this invention to ensure that the secure adaptor could be screwed into the giving set port but not easily removed.

The dip tubing of the sterile surgical spray unit would normally be made from flexible polythene/plastic tubing. This could be of the correct length to reach the bottom of, for example, the 1 litre topical cleansing solution plastic pour bottle and because of the dip tubings flexibility it would tend to spread over the bottom of the smaller

(500 ml) container to enable a standardised sterile surgical spray unit to be used on several different sized topical cleansing solutions plastic pour bottles.

The same is true of the intravenous fluid packs or irrigation packs where the dip tubing could be designed of a length to reach the bottom of the larger (eg: 1 litre) bag, but also spread over the bottom of the pack to be suitable for smaller (eg: 500 ml) packs. The dip tubing could be cut using sterile techniques to allow its use with small specialised 'minibag' small volume intravenous solutions.

This invention uses a manually operated trigger sprayer. In further adaptations of this invention disposable electrical or mechanical pumps could be used.

The secure adaptor can also be used in conjunction with the giving set port of sterile irrigation fluid packs such as the 0.9% sodium chloride for irrigation pack made by Baxter Healthcare.

In the design of this giving set port the polythene tube is lengthened compared with the intravenous giving set port of the intravenous fluid packs.

The secure adaptor can be specifically designed for such packs as shown in Fig 7 in which the secure adaptor uses



a smooth plastic tube to connect against the inner surface of the polythene tube of the giving set tube. The adaptor could have a very strong push fit using this type of giving set port as the increased length increases the friction of the push-fit arrangement and hence its security of fit.

In an alternative design, Fig 8, a small screw thread is placed at the top of the adaptor for a final secure screw thread. This screw thread uses the design features previously described to reduce the possibilities of leakage around the top of the giving set port. These features include the fact that the screw thread is cut into the adaptor and thus ends beneath the external contact surface of the adaptor. This prevents leakage via the screw thread.

The adaptor can also incorporate a concentric ring or 'stop' which acts as a further design feature to prevent leakage of the irrigation fluids from the irrigation fluid pack.

When this adaptor is pushed into the giving set port of the irrigation fluid pack the polythene tubing expands over the adaptor.

The polythene tubing would also expand over any concentric rings or stops incorporated in the design. The polythene tubing would also expand over any screw thread incorporated

into the design. As the screw thread ends by being cut into the adaptor the polythene tubing fits tightly over it. The design can also incorporate a 'shoulder' 14, which acts as a further design feature to prevent leakage of the irrigating fluid from the irrigation fluid pack.

The design features mentioned in this patent can be incorporated into the specific design of a secure adaptor for the designs of giving set ports of all proprietary intravenous and irrigating sterile fluid packs. The length and diameter of the adaptor can be subtly altered to accommodate the slight changes in such giving set port designs.

Some giving set ports need to be cut with sterile scissors before introducing the secure adaptor.

Some sterile fluid packs have additive ports which are very suitable for the introduction of a secure adaptor.

Some giving set ports have seals which are at differing distances from the outside and of varying internal diameters. The specific design of the secure adaptors can be subtly varied in terms of external diameters, length and screw thread type for each varied design of giving port or additive port. All these subtly different designs of secure adaptor will incorporate the design features described in this patent.

The adaptors 4 and 5 of this sterile spray unit can be joined to a suitable eye bath, 28. See Fig 10. This eye bath can incorporate a simple deflector, 29, to prevent high pressure lavage and the eye can thus be gently bathed in sterile saline or other suitable sterile fluids. The unit can be designed to be self administered and this has a great number of First Aid applications. See Fig 11. The eye bath can twist round through 180 degrees using the simple joint, 30, so that the eyebath can be used conveniently for both left and right eyes. In an alternative design an eyebath can be screwed directly on to the thread of a "pour bottle" using the "sterility security device" which enables the eye bath to be screwed-on to the pour bottle but not screwed off. This is illustrated in Fig 9. The eyebath can be filled either by pouring the bottle or in an alternative design by squeezing the bottle to fill the eyebath via dip tubing, 32.

For First Aid use the sterile water for irrigation pour bottles can incorporate a redesigned plastic top to give the plastic top a secondary use as an emergency eye bath. This design is illustrated in Fig 20. The standard plastic top of the pour bottle 46, incorporates flexible lugs, 49. When this plastic top is screwed-on to the irrigation pour bottle these flexible lugs, 49, are pushed over the top of a flange 50, and when subsequently screwed-off a seal is broken and the sterile water for irrigation becomes available for use. In its present design the top does not hold water and hence is not suitable for use as an

emergency eye bath

The standard plastic top can be redesigned by using a further plastic or rubber cap 48, which fits tightly over the existing plastic top 46. The standard plastic top and the rubber or plastic sleeve can be screwed-on to the pour bottle, the lugs, 49, engage the flange, 50, and can be screwed-off breaking the seal and thus allowing the sterile water to be used for an emergency eye wash to flush out a foreign body e.g. a spark or e.g. to wash away a caustic splash. The open end of the cap, 51, is designed to fit snugly around the eye socket. In an alternative design, 47, the plastic top is redesigned to form a new one piece plastic cap in which a plastic cover, 52, has been added to the existing cap design. The lugs, 49, are still able to push over the flange, 50, but the whole cap is now watertight and hence it can be used as an emergency eye bath. The open end of the cap can be designed to fit the eye socket snugly. This redesigned plastic top can be produced in clear plastic so that any foreign body can be visualised and the mechanism of action can be more readily understood by the user who can visualise the flexible lugs, 49, contacting the flange, 50. This design is shown in Fig 20. In a first aid emergency it is envisaged that the newly designed irrigation pour bottle could be rapidly screwed-on and then screwed-off the pour bottle. The sterile fluids would then be available for pouring directly on to the eye from the pour bottle or else available to be poured into the newly designed plastic top which could act as an

emergency eye bath.

The sterile surgical spray unit can pump sterile saline from an intravenous fluid pack via a specialist adaptor, 4 or 5, into a suitable intravenous catheter. Thus a method of rapid intravenous fluid administration is produced which may be suitable for severely shocked patients. Alternatively if a suitable drug is placed into the intravenous fluid pack via the additive port the patient can choose the speed at which the medication is given intravenously eg: if a powerful painkiller eg: pethidine is added to the intravenous fluid pack the patient can choose the timing of administration of the pain killer for the most effective personally controlled pain relief.

The sterile spray unit can be joined to a soft, small brush which can be used to lavage heavily contaminated wounds. The sterile fluid can be directed between the bristles as shown in Fig 12.

The sterile spray unit can also be joined to a porous comb as shown in Fig 13. Such a comb could be joined eg: to the sterile fluids or to a fluid container with suitable insecticide for treating head lice in people and lice and fleas in animals.

A teaching aid for teaching medical personnel such as doctors, nurses, dental surgeons, dental nurses, veterinary surgeons and veterinary nurses has been designed to

demonstrate the use of the surgical spray unit. This teaching aid is produced in the form of a ceramic tile. There are designs on this tile which are representative of major wound types.

Fig 14 shows this teaching aid in the form of a ceramic tile. The surface of the tile can be transfer printed with a variety of titles, logos and instructions, 33.

A shallow, roughly circular indentation in the surface of the tile, 34, can represent a leg ulcer. A deeper cut in the surface of the tile can represent a deep wound, 35. An irregular laceration can be represented as, 36.

37 represents a deep puncture wound.

The bulk of the surface of the tile can be glazed. Various coloured glazes can be used. Red glazes can be used to represent haemorrhage. Yellow for an infected wound area and the overall surface of the tile could be in skin colour. The shaded areas of Fig 14 represent unglazed, more porous areas.

The invention can be used as a teaching aid for the medical/veterinary professions as follows: If a liquid detergent eg: Fairy Liquid (trademark) is applied to the various types of wound representation then it will tend to soak in to those porous, non-glazed areas. When wound lavage is applied to these representational wounds then the

nurse, doctor, veterinary surgeon or veterinary nurse will have an indication of the quantity of wound lavage fluid that must be used and an idea of the correct pressures of wound lavage which must be applied to clean the wound as the liquid detergent produces froth and detergent bubbles when the wound lavage is applied, and this model for wound lavage would be effective in advocating that lavage is complete when the frothy bubbles are no longer being produced.

This teaching aid would be particularly effective in demonstrating the sterile surgical spray unit as described in UK Patent No 9323080.3.

The design of this teaching aid could be adapted by altering the amount of unglazed to glazed area on the ceramic tile.

## CLAIMS

1. A lavage device comprising;  
pump means [1] having a liquid inlet and a spray outlet,  
and an annular connector [18] surrounding the liquid inlet;  
a container [7] for lavage liquid, having an outlet port  
[8] ;  
a hollow adaptor [2] having a first limb adapted for  
connection with the outlet port of the container, and a  
second limb adapted for connection with the annular  
connector on the pump means;and  
a dip tube [9] extending from the pump inlet, through the  
hollow adaptor, into the container.
2. A device according to claim 1, in which the pump means  
is mounted in a housing, and the annular connector is  
formed on the housing.
3. A device according to claim 1 or 2, in which the container



is a plastics pouch having a tubular neck into which the first limb of the adaptor is pushed.

4. A device according to claim 3, in which the first limb of the adaptor has its external surface shaped to stretch, at least locally, the walls of the neck.

5. A device according to claim 4, in which the first limb of the adaptor has a tapered surface and/or its surface has outwardly directed barbs, ribs or screw threads.

6. A device according to any one of claims 1 to 5, in which the annular connector and the second limb of the adaptor have complementary screw threads or bayonet fittings or other latching means.

7. A device according to claim 6, in which the annular connector includes a ratchet fitting that allows the annular connector to be screwed on to the second limb of the adaptor, but prevents it from being unscrewed.

8. A kit comprising a sterilizable package containing a pump means, adaptor, and dip tube as claimed in any one of claims 1 to 7.

9. A kit according to claim 8, including one or more further adaptors for attachment to the spray outlet, for connecting the pump to cannulae, tubing or hypodermic needles.

10. A kit according to claim 8 or 9, in which the components are packed in a tray having one or more edges shaped to conform with a patients body, to act as a drainage receptacle.

11. An adaptor for use with a container of lavage liquid, comprising a first hollow limb for connecting to the neck

of a giving set port of a sterile liquid pack and which has an external surface which is tapered and/or has outwardly directed barbs, ribs or screw threads, and a second hollow limb in communication with the first limb and which has;

[a] an external surface which is tapered and /or has outwardly directed barbs , ribs or screw threads, or

[b] an annular connector , or

[c] an enema nozzle.

12. An adaptor according to claim 11, in which the first limb of the adaptor is tapered with a coarse external thread to engage the giving set port of a sterile liquid pack, and the end of the first limb is shaped so as to cut through a seal closing the port.

13. An adaptor according to claim 12, in which the start of the screw thread is spaced from the end of the first limb so that the thread engages the walls of the port as the shaped end of the limb contacts the seal in the port.

14. An adaptor according to claim 12 or 13, in which the first limb includes a sealing collar that is forced into the port by the screw action.

15. An adaptor according to any one of claims 12 to 14, in which the second limb of the adaptor includes a ratchet fitting that allows the adaptor to be screwed on to the giving set port, but prevents it from being unscrewed.

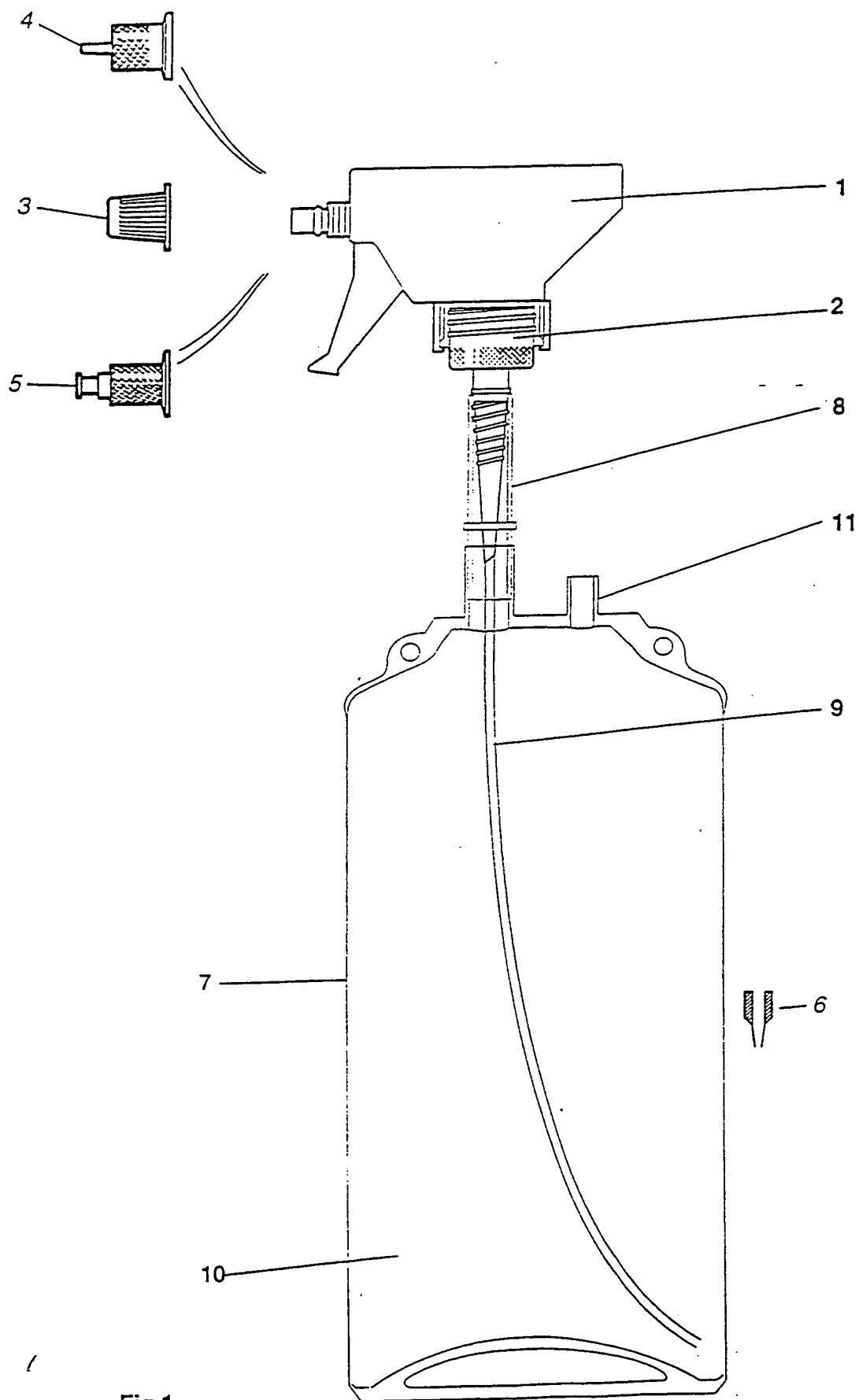


Fig 1

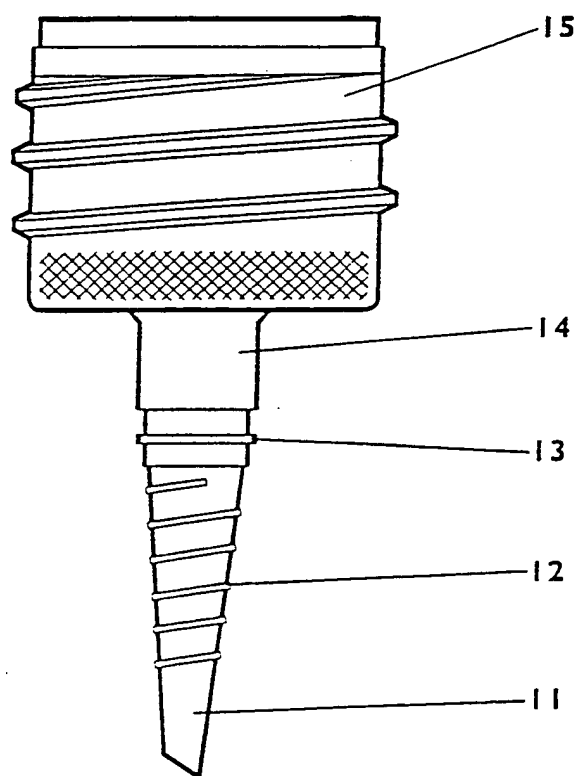


Fig.2

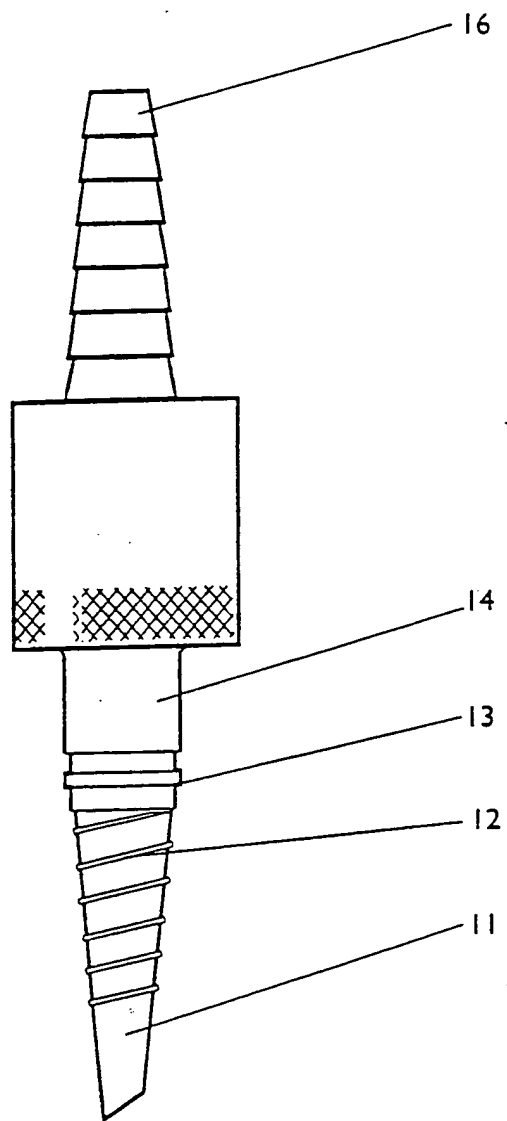


Fig 3

4/19

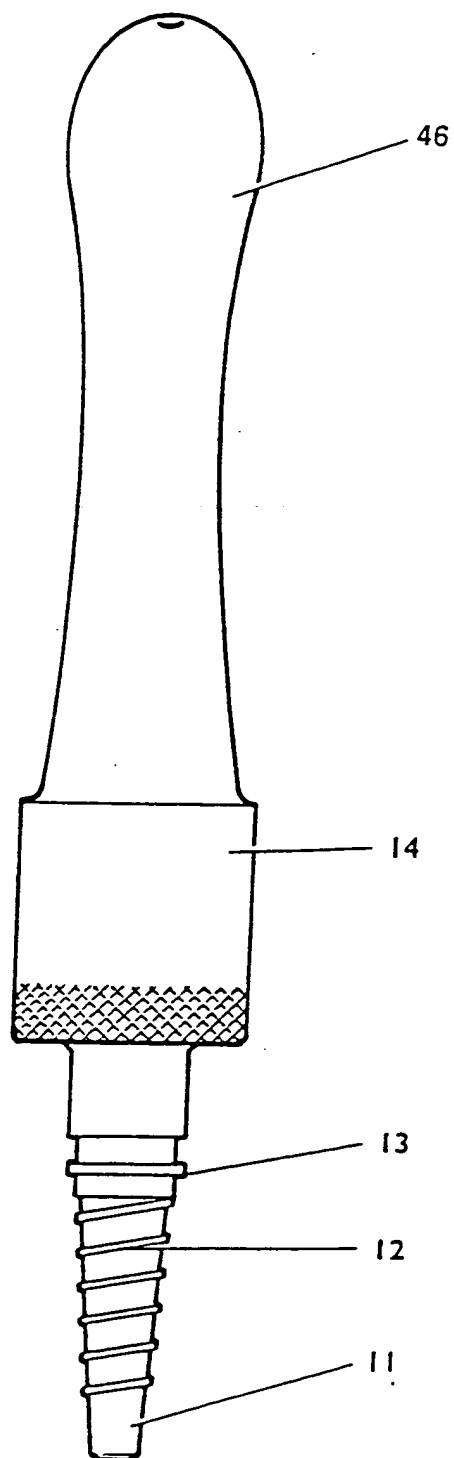


Fig 4.

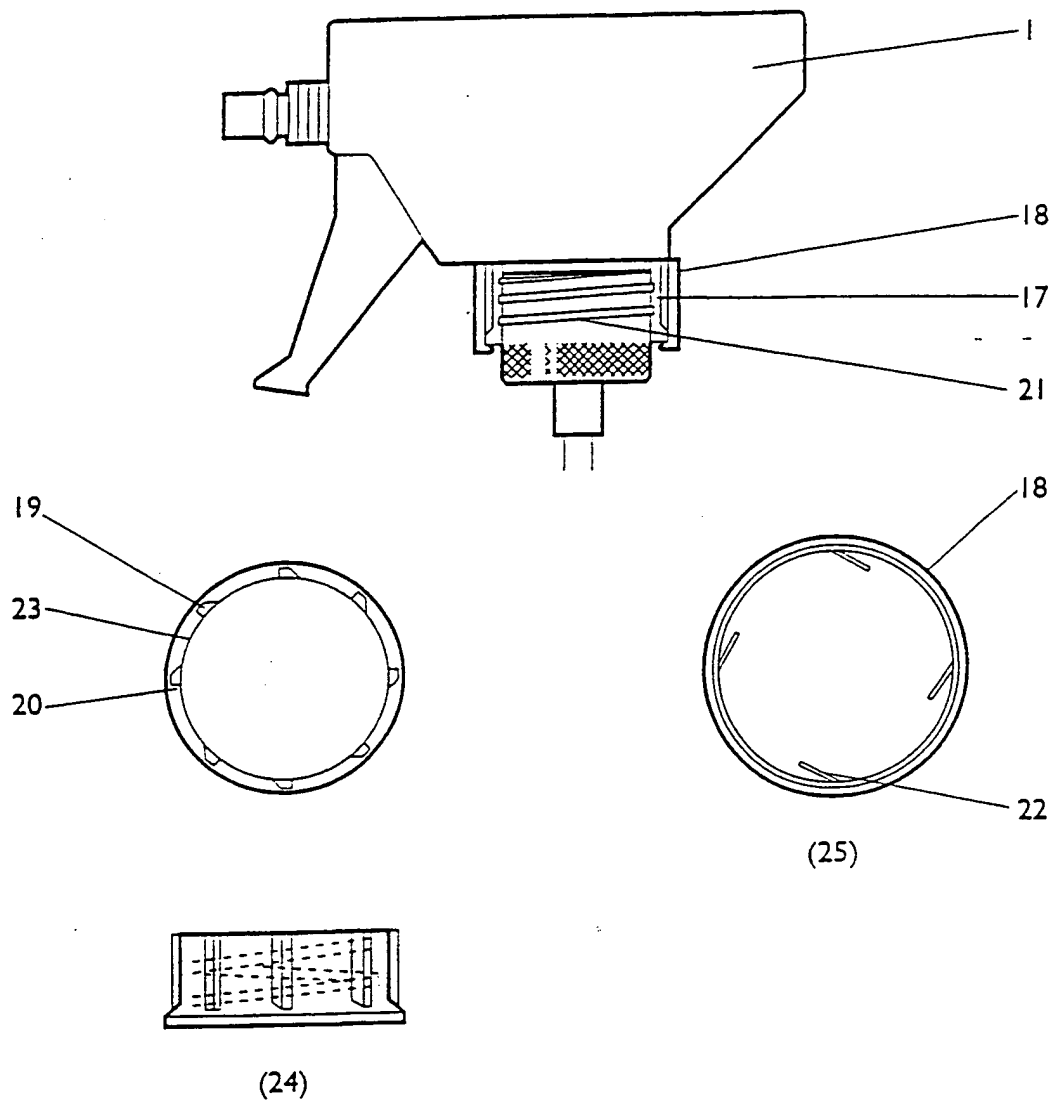


Fig 5

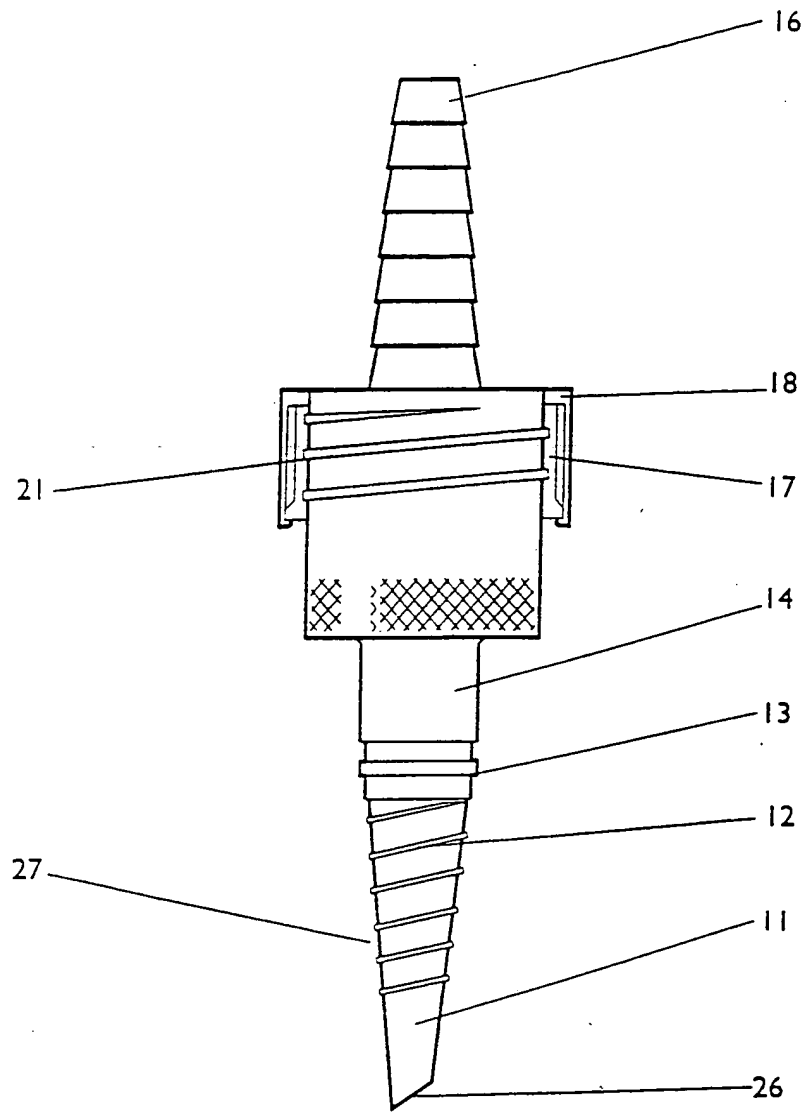


Fig 6



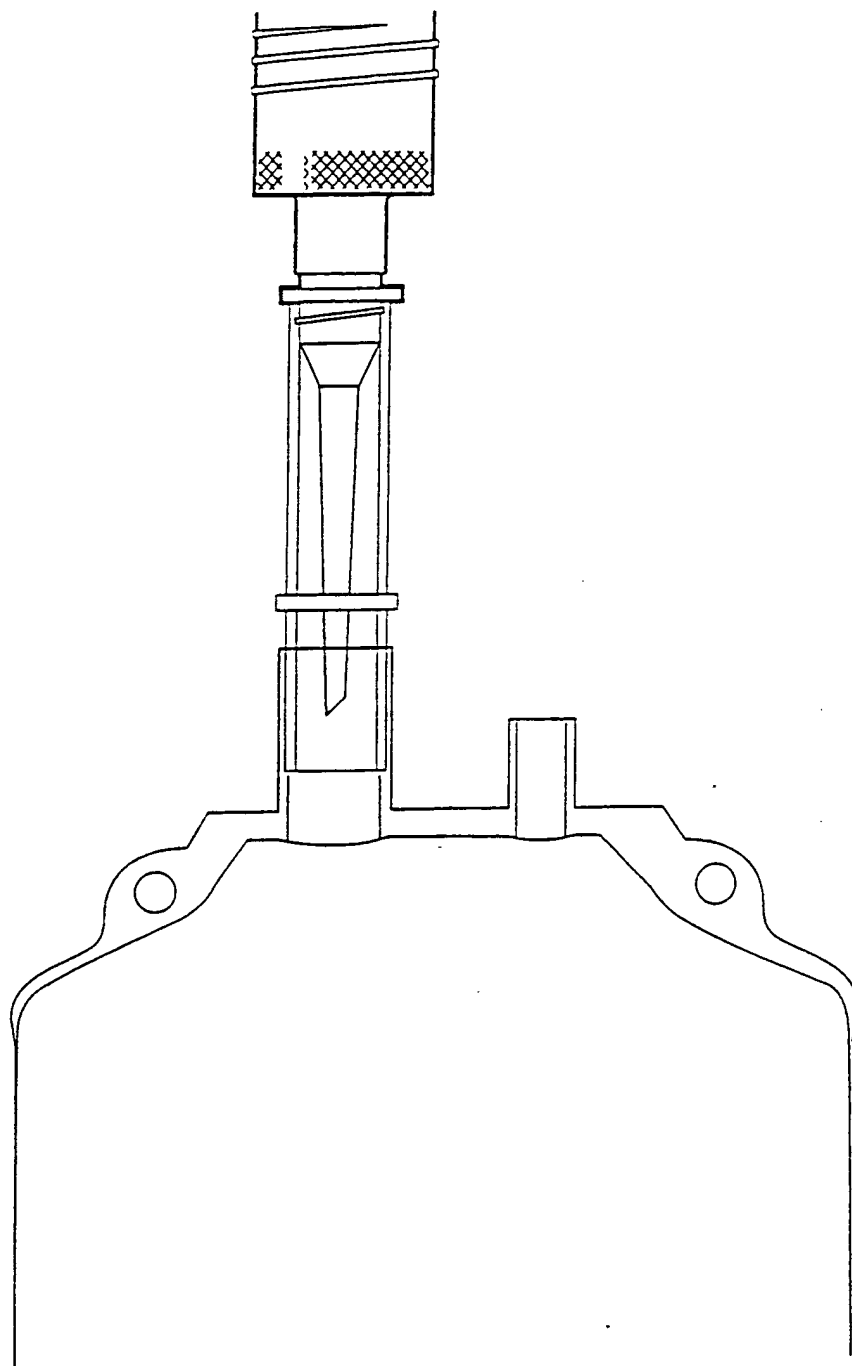


Fig 7

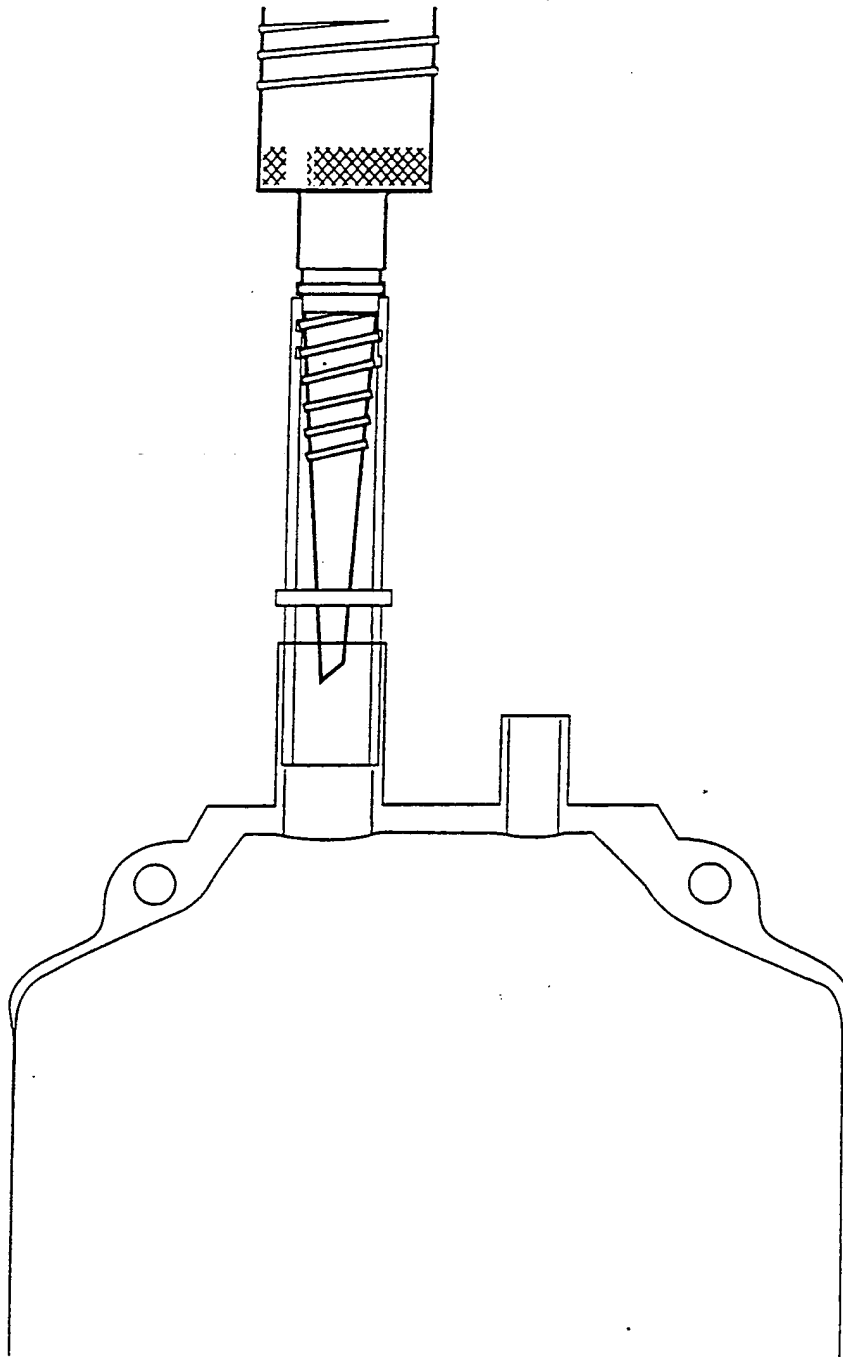


Fig 8

9/19

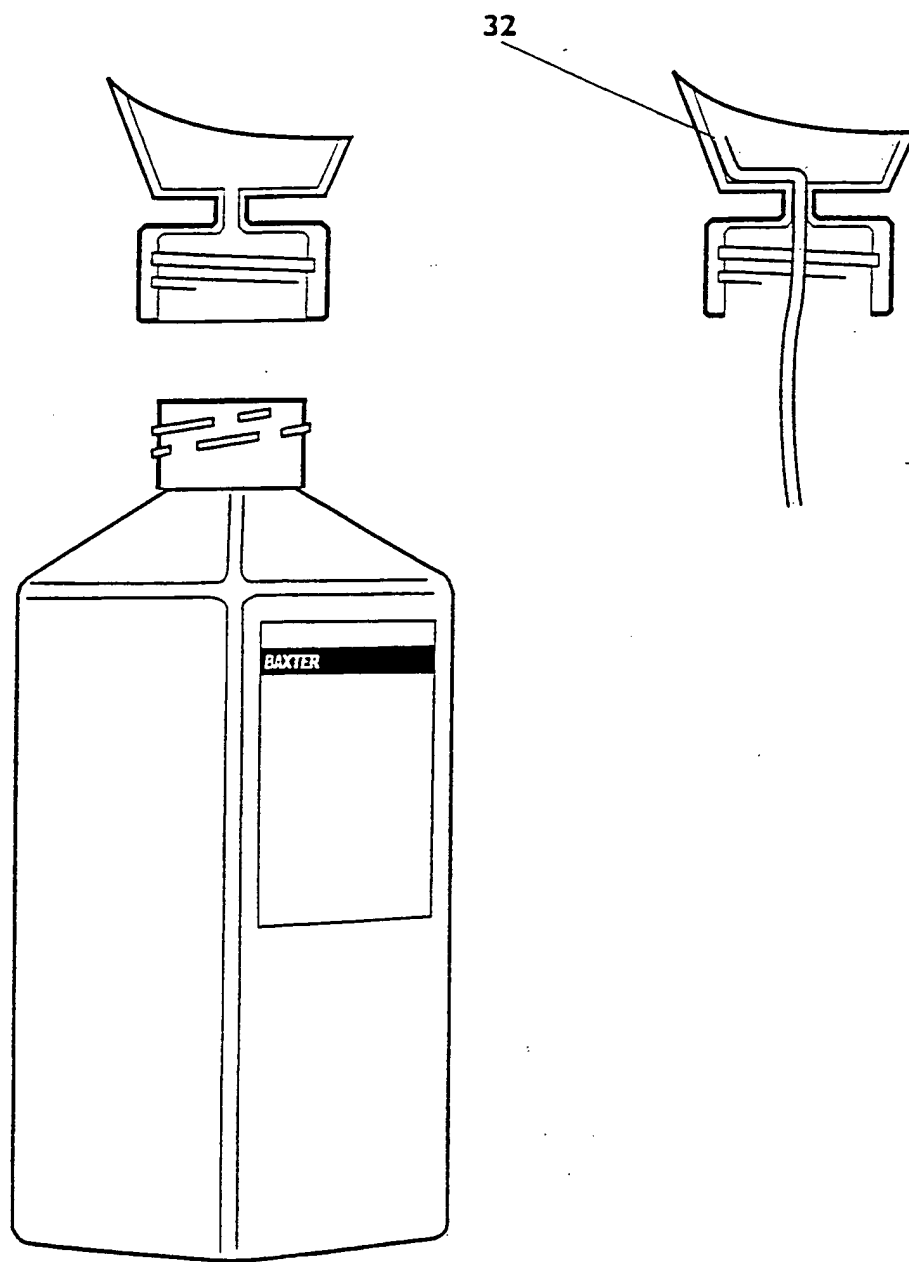


Fig.9

10/19

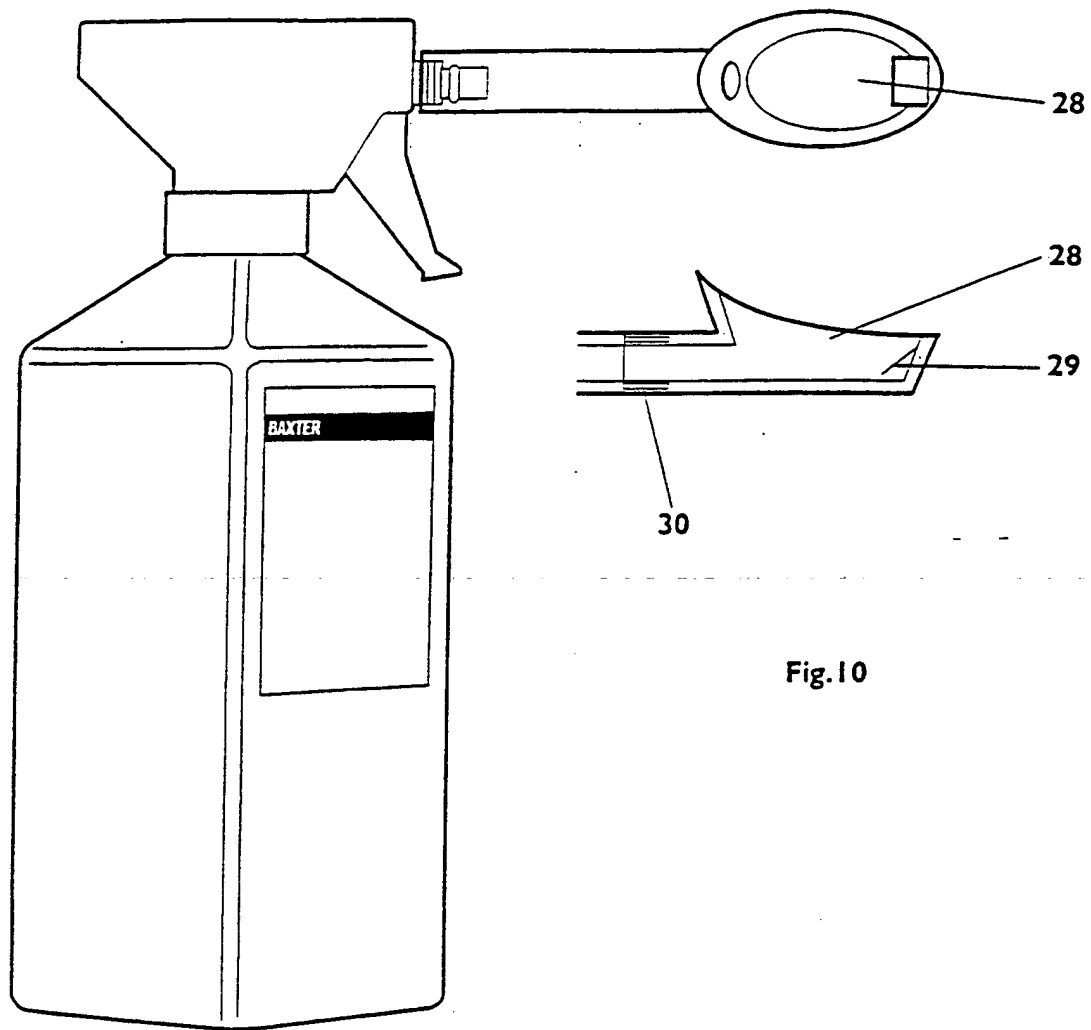


Fig. 10

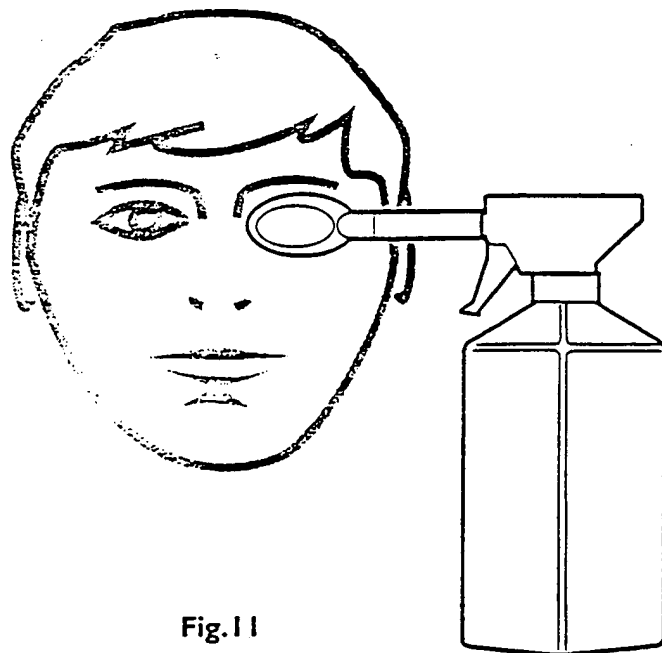


Fig. 11

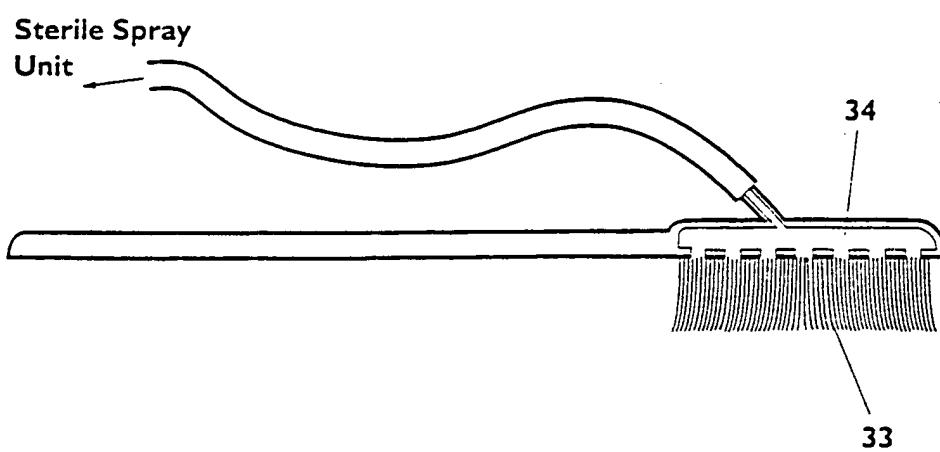


Fig. 12

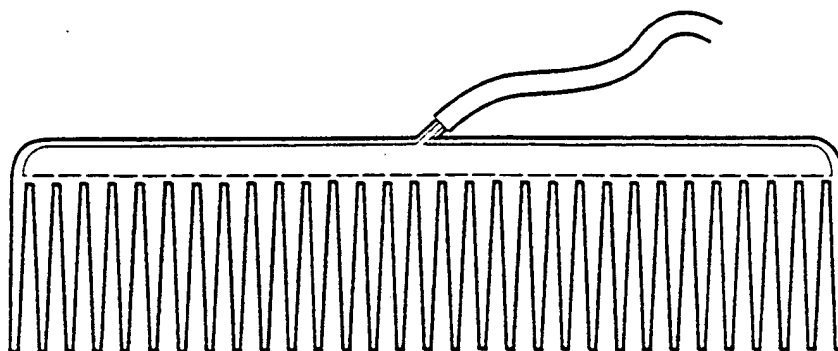
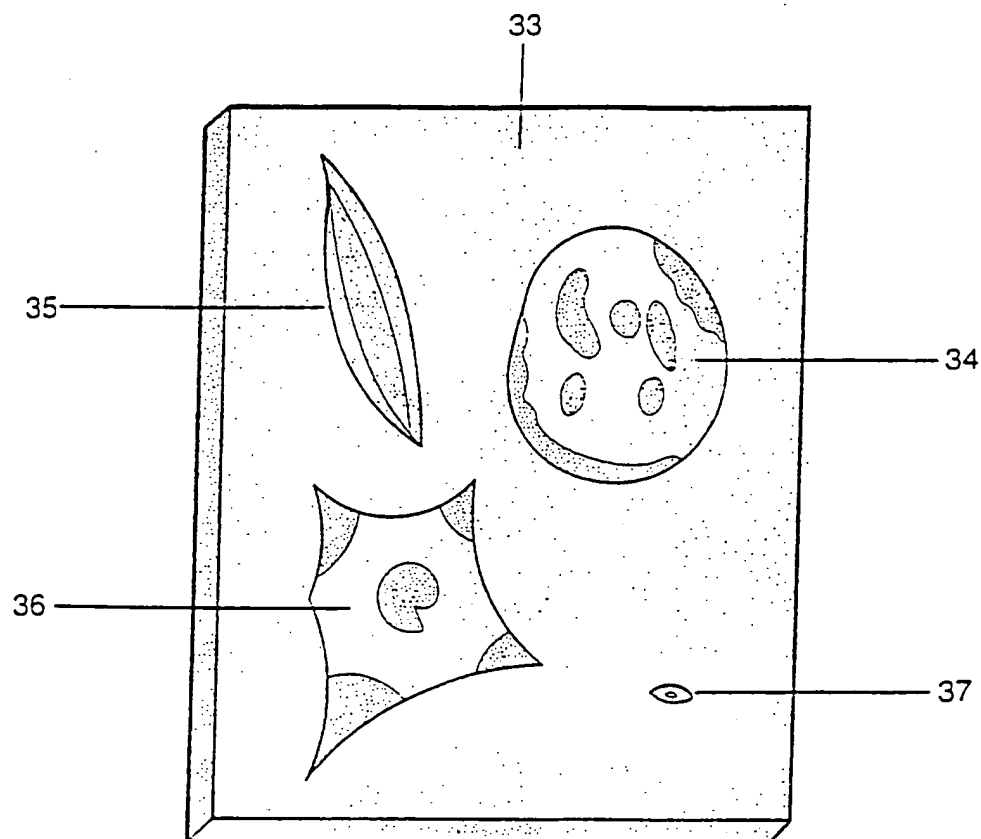


FIG. 13

Fig 14



14/19

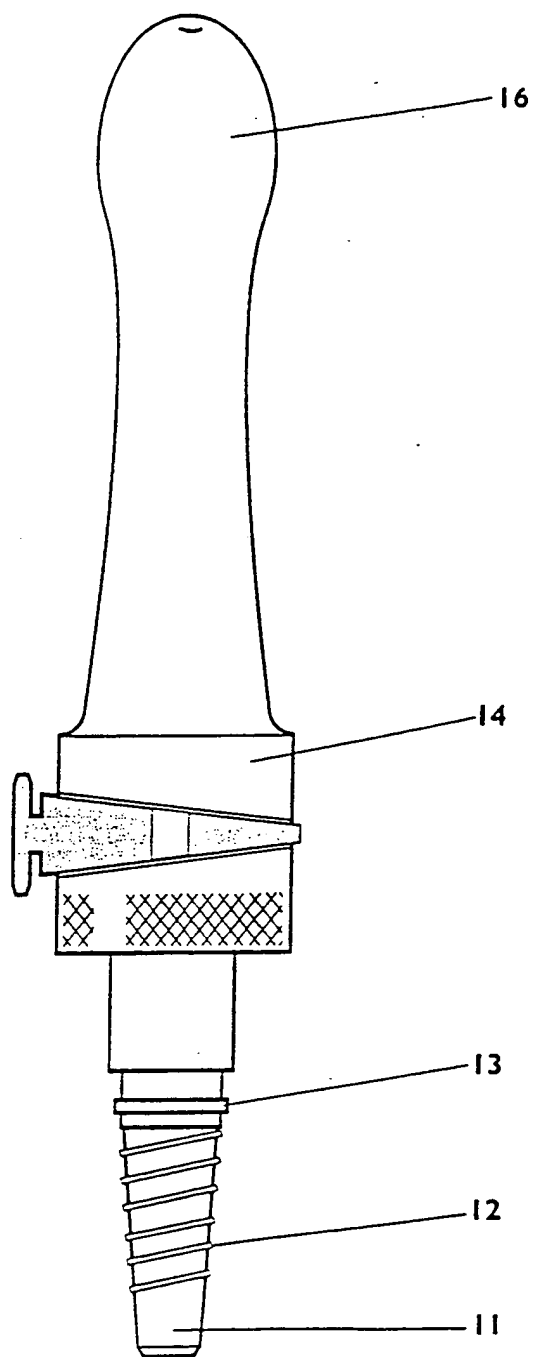


Fig.15



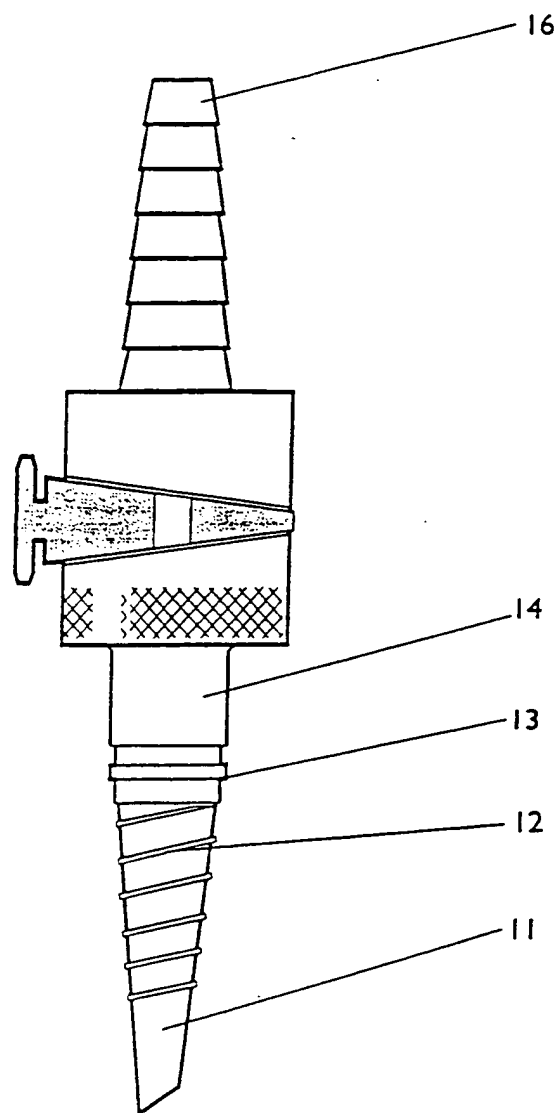


Fig 16

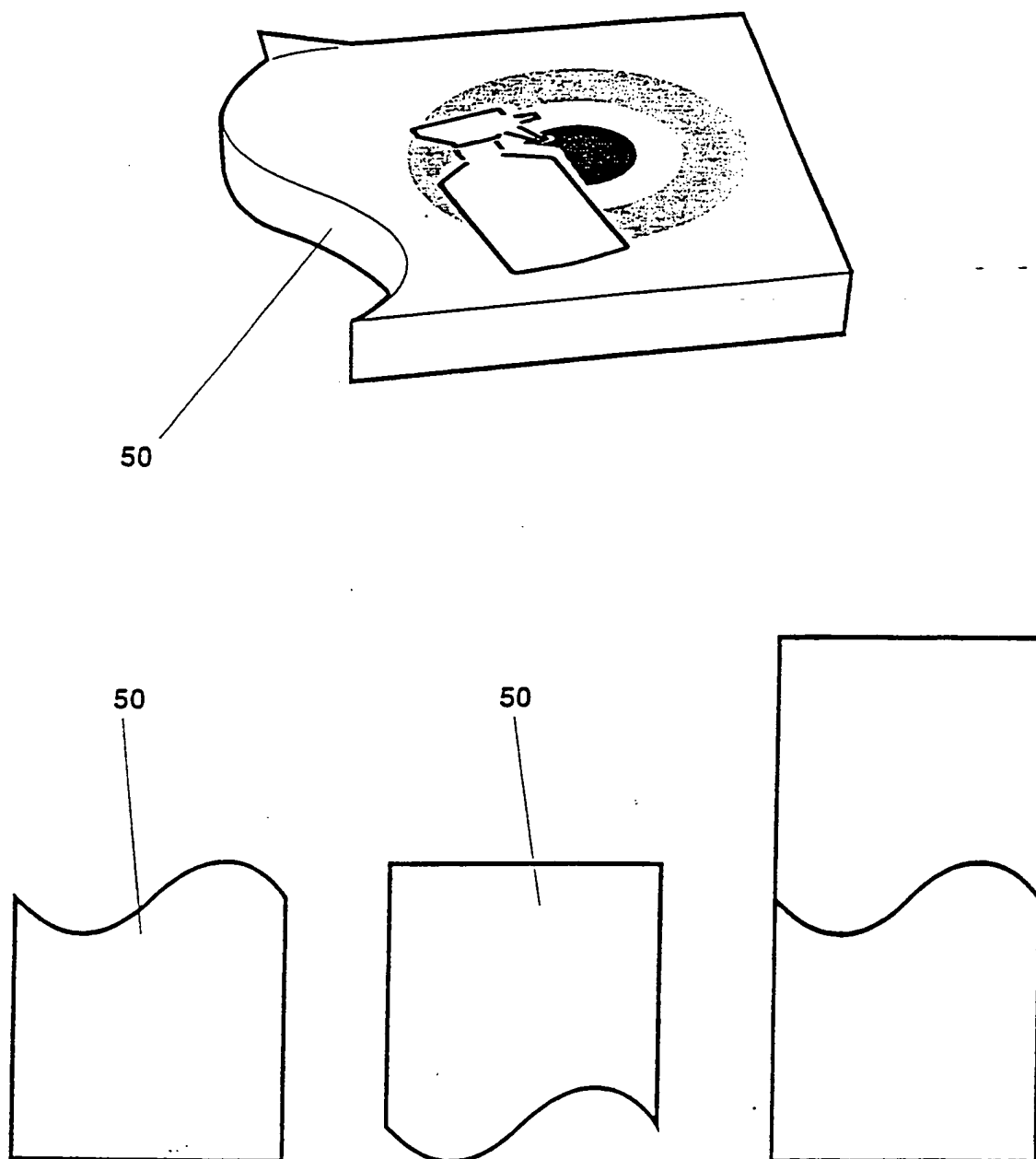


Fig 17

17/19

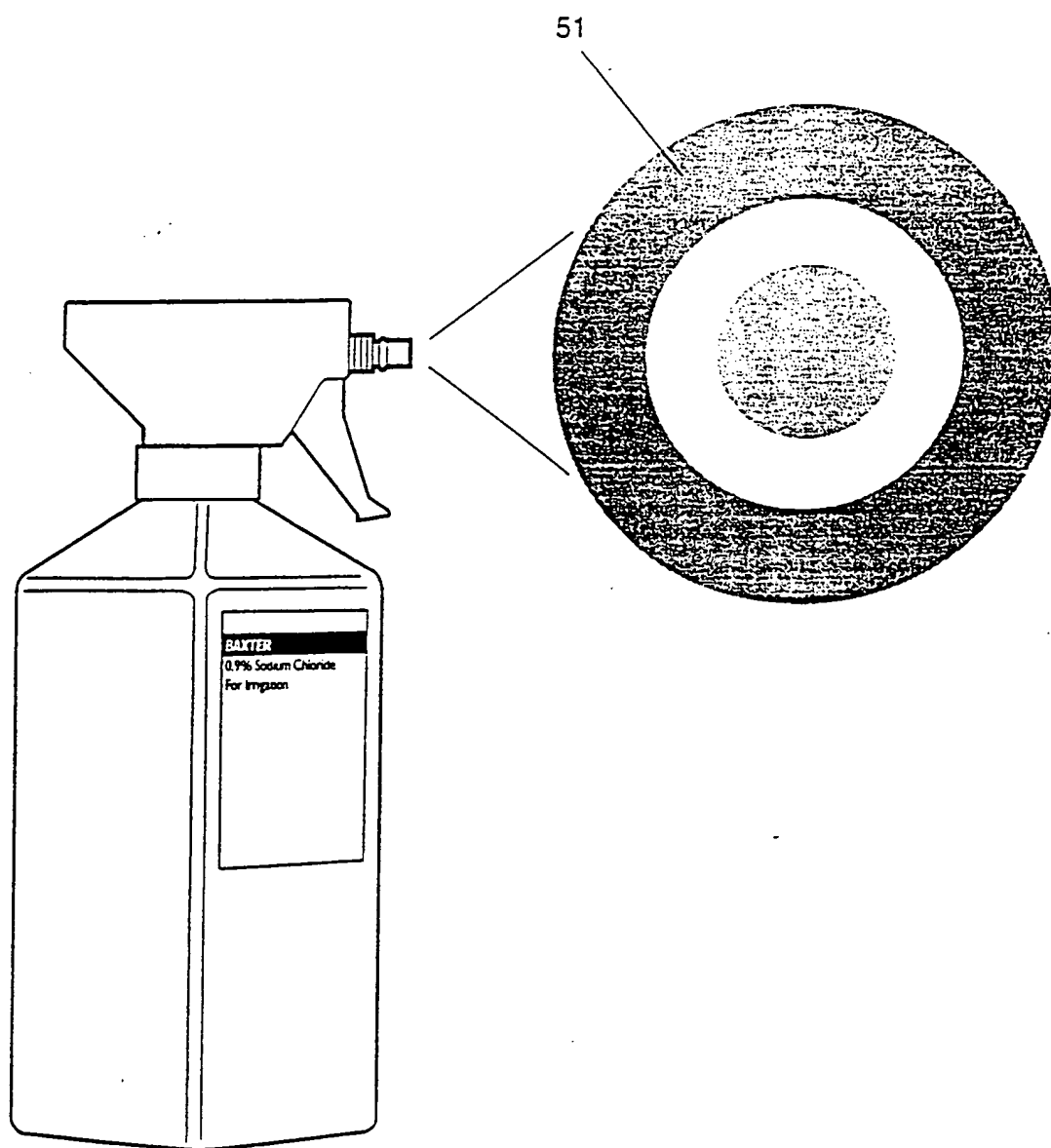


Fig 18



19/19

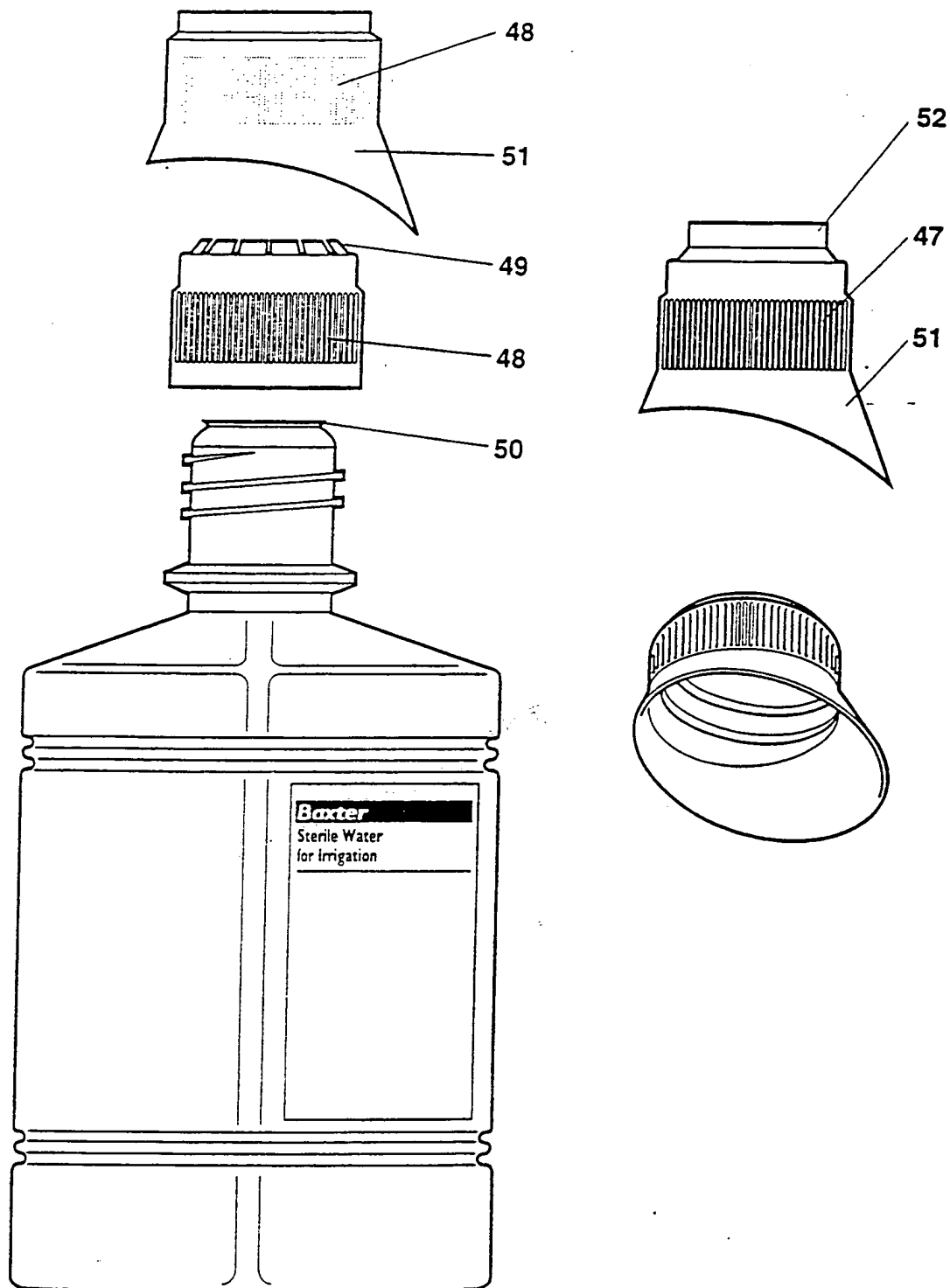


Fig 20

**THIS PAGE BLANK (USPTO)**